MAR 0 6 2013

510(k) Summary
NAUTILUS Spinal System

Submitted By: Life Spine, Inc.
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Date Prepared: October 25th, 2012

Trade Name: NAUTILUS Spinal System

Common Name: Pedicle Screw Spinal System

Classification: NKB, CFR 888.3070, Class III
MNH, CFR 888.3070, Class II
MNI, CFR 888.3070, Class II

Predicate Device: NAUTILUS Spinal System (K111953)
CONQUEST Spinal System (K080767)
ARX Spinal System (K061600)

Device Description:

The NAUTILUS Thoracolumbar Spinal System consists of an assortment of rods, screws, cross connectors, and axial and offset connectors. The bone screw, head, and taper lock are assembled together during manufacturing to create the NAUTILUS Thoracolumbar Spinal System screw assembly component. The cross, axial, and offset connectors are also assembled during manufacturing. The NAUTILUS Thoracolumbar Spinal System implant components are made from titanium alloy (Ti-6Al-4V ELI) as described by ASTM F136. Do not use any of the NAUTILUS Thoracolumbar Spinal System components with the components from any other system or manufacturer.

Intended Use of the Device:

Internal fixation implants are load-sharing devices intended to stabilize and maintain alignment until normal healing occurs. Implants are not intended to replace normal body structures or bear the weight of the body in the presence of incomplete bone healing.

The NAUTILUS Spinal System, when properly used, is intended for posterior pedicle screw fixation of the non-cervical posterior spine in skeletally mature patients. It provides stabilization and immobilization of spinal segments as an adjunct to fusion.

When used as a posterior spine thoracic/lumbar system, the NAUTILUS Spinal System is indicated for one or more of the following: (1) degenerative disc disease (is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), (2) trauma (i.e. fracture or dislocation), (3) curvatures (scoliosis, kyphosis, and/or lordosis), (4) spinal tumor, (5) failed previous fusion (6) pseudoarthrosis, (7) spinal stenosis, (8) spondylolisthesis.

Technological Characteristics:

The NAUTILUS Spinal System is substantially equivalent to the predicate systems in terms of design, materials, indications for use and sizing.

Material:

The NAUTILUS Spinal System is 6AL-4V-ELI titanium manufactured according to ASTM F136. The device is comprised of a variety of non-sterile titanium, single use components.

Performance Data:

Static torsion, static compression bending, and dynamic compression bending testing per ASTM F1717 was presented to demonstrate the substantial equivalency of the NAUTILUS Spinal System.

Conclusion:

The information presented demonstrates the substantial equivalency of the Nautilus Spinal System

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

March 6, 2013

Life Spine, Incorporated
% Mr. Randy Lewis
Director, Regulatory Affairs/Quality Assurance
2401 West Hassell Road, Suite 1535
Hoffman Estates, Illinois 60169

Re: K123373
Trade/Device Name: NAUTILUS Spinal System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class III
Product Code: NKB, MNI, MNH
Dated: February 14, 2013
Received: February 15, 2013

Dear Mr. Lewis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, Misbranding by reference to premarket notification (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htmfor the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin D. Keith

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) number (if known): K123373

Device Name: NAUTILUS Spinal System

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Prescription Use x	And/Or	Over-the-Counter Use
(Part 21 CFR 801 Subpart D)		(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Ronald P. Jean -S

(Division Sign-Off)
Division of Orthopedic Devices
510(k) Number: K123373